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10/750,439	12/31/2003	Christopher M. Meek	ZIM0400	1791

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EXAMINER

GEORGE, TARA R

ART UNIT	PAPER NUMBER
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3733

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/750,439	Applicant(s) MEEK, CHRISTOPHER M.	
	Examiner Tara R. George	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4 and 6-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4 and 6-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation "the box area" in line 1. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Timoteo (6168629) in view of Chiang (5732606) and in further view of Hoffman (7131973).

With respect to claim 1, Timoteo teaches an orthopedic implant having a fastener receiving portion (5, 6, 7 and 8) for receiving a fastener (18, 19) along a fastener axis (see fig. 1 and note dashed line extending from 20 and 21), a portion of the implant overhanging the fastener receiving portion (see fig. 1). Timoteo teaches the claimed

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invention except for explicitly teaching the driver required by claim 1. However, it is noted that using a driver to drive fasteners into an implant is well known in the art and it would have been obvious to one of ordinary skill in the art at the time of the invention that any driver mechanism can be used to drive the fasteners of Timoteo into the implant of Timoteo. Chiang teaches a flexible screwdriver (see fig. 3) comprising a shaft having a fastener engaging end (50), a driven end (10), an intermediate portion (40), the shaft structured and arranged such that during application of the rotational forces to the driven end the intermediate portion rotates about the longitudinal axis (see fig. 3 and col. 1 lines 30-45), in order to provide a driver that is easily used to drive a fastener (see col. 1 lines 10-19 and 22-29). It would have been obvious to one of ordinary skill in the art at the time of the invention to drive the fasteners of Timoteo into the implant of Timoteo with the driver of Chiang in order to provide a system that allows easy implantation of an orthopedic implant.

The combination of Timoteo in view of Chiang teaches the claimed invention except for explicitly stating the shaft having a longitudinal axis between the fastener engaging end and the driven end, an intermediate portion offset radially away from the axis, and an engaging end and driven end coaxial for transmission of longitudinal forces along the axis and rotational forces about the axis from the driven end to the engaging end. It is noted that Chiang does teach a flexible shaft that is bendable to form a curved shape in order to reach the fastener. Hoffman teaches a driver with shaft having a fastener engaging end 240, a driven end (226), an intermediate end (232), a longitudinal axis between the fastener engaging end and the driven end (see fig. 3A),

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the intermediate portion offset radially away from the axis (see fig. 3A), the engaging end and driven end being coaxial for transmission of longitudinal forces along the axis and rotational forces about the axis from the driven end to the engaging end (see fig. 3A), in order to provide a shaft that is shaped to drive the fastener and allow insertion into areas difficult to access (see col. 5 lines 47-61 and note that Hoffman teaches different shapes of the shaft in figs. 3A and 13). It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the shaft of the combination of Timoteo in view of Chiang with the shaft having a longitudinal axis between the fastener engaging end and the driven end, an intermediate portion offset radially away from the axis, and an engaging end and driven end coaxial for transmission of longitudinal forces along the axis and rotational forces about the axis from the driven end to the engaging end, in further view of Hoffman, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a driver with a shaft that allows for easy insertion. In re Dailey and Eilers, 149 USPQ 47 (1966).

As for claim 4, the combination of Timoteo in view of Chiang and in further view of Hoffman further teaches wherein the shaft is able to transmit torsional input from the driven end to the engaging end and the offset position is shaped to extend around the overhanging portion such that the driver is rotatable to turn the fastener and the offset portion clears the overhanging portion of the implant (as stated in the rejection with respect to claim 1).

Claims 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Justin et al. (2003/0225457) in view of Chiang (5732606) and in further view of Hoffman (7131973).

With respect to claim 7, Justin teaches a femoral prosthesis of an articulating knee joint implant including an anterior patellar flange (24), a distal condyle (28), and a posterior condyle (30) forming an exterior articular surface, the implant having an interior box area (between 26 and 22) having an anterior box surface opposite the anterior patellar flange (26), a distal box surface opposite the distal condyle (near 32), and a posterior box surface opposite the posterior condyle (near 34), the distal box surface having a distal fastener receiving portion (32) for receiving a fastener (36) along a distal fastener axis (see dashed lines extending from 36) and the posterior box surface having a posterior fastening receiving portion (32) for receiving a fastener (38) along a posterior fastener axis (see dashed lines extending from 38) transverse to the anterior box surface, the patellar flange having a patellar flange height measured from the posterior fastener axis to an apex (near ref. 29 in fig. 3) of the patellar flange perpendicular to the posterior fastener axis, the posterior condyle having a posterior condyle height measured from the distal box surface to an apex of the posterior condyle perpendicular to the distal box surface. Justin teaches the claimed invention except for explicitly teaching the driver required by claim 1. However, it is noted that using a driver to drive fasteners into prosthesis is well known in the art and it would have been

obvious to one of ordinary skill in the art at the time of the invention that any driver mechanism can be used to drive the fasteners of Justin into the prosthesis of Justin.

Chiang teaches a flexible screwdriver (see fig. 3) comprising a shaft having a fastener engaging end (50), a driven end (10), an intermediate portion (40), the shaft structured and arranged such that during application of the rotational forces to the driven end the intermediate portion rotates about the longitudinal axis (see fig. 3 and col. 1 lines 30-45), in order to provide a driver that is easily used to drive a fastener (see col. 1 lines 10-19 and 22-29). It would have been obvious to one of ordinary skill in the art at the time of the invention to drive the fasteners of Justin into the prosthesis of Justin with the driver of Chiang in order to provide a system that allows easy implantation of prosthesis.

The combination of Justin in view of Chiang teaches the claimed invention except for explicitly stating the driver further comprising a shaft axis, an intermediate portion having a first bend, a second bend offset radially from the shaft axis a second distance, and a third bend axially spaced a third distance from the fastener engaging end, the shaft structured and arranged such that during application of the rotational forces to the driven end the second bend rotates about the longitudinal axis. Hoffman teaches a driver with shaft having a fastener engaging end (626), a driven end (620), an intermediate end (612), a shaft axis between the fastener engaging end and the driven end (see fig. 13- extending from 620 through 626), an intermediate portion having a first bend (near 617), a second bend offset radially from the shaft axis a second distance (near 654), and a third bend (near 622) axially spaced a third distance from the fastener

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engaging end, the shaft structured and arranged such that during application of the rotational forces to the driven end the second bend rotates about the longitudinal axis in order to provide a shaft that is shaped to drive the fastener and allow insertion into areas difficult to access (see col. 5 lines 47-61 and note that Hoffman teaches different shapes of the shaft in figs. 3A and 13). It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the shaft of the combination of Justin in view of Chiang with the driver further comprising a shaft axis, an intermediate portion having a first bend, a second bend offset radially from the shaft axis a second distance, and a third bend axially spaced a third distance from the fastener engaging end, the shaft structured and arranged such that during application of the rotational forces to the driven end the second bend rotates about the longitudinal axis, in further view of Hoffman, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a driver with a shaft that allows for easy insertion. In re Dailey and Eilers, 149 USPQ 47 (1966).

As for claim 8, it is noted that the combination of Justin in view of Chiang and in further view of Hoffman teaches the claimed invention except for explicitly stating wherein the second distance is equal to or greater than the patellar flange height such that the driver is engageable with a fastener along the posterior fastener axis with the intermediate portion of the shaft clearing the apex of the patellar flange. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the shaft of the combination of Justin in view of Chiang and in further view

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of Hoffman wherein the second distance is equal to or greater than the patellar flange height such that the driver is engageable with a fastener along the posterior fastener axis with the intermediate portion of the shaft clearing the apex of the patellar flange, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

As for claim 9, it is noted that the combination of Justin in view of Chiang and in further view of Hoffman teaches the claimed invention except for explicitly stating wherein the first distance is equal to or greater than the posterior condyle height such that the driver is engageable with a fastener along the distal fastener axis with the intermediate portion of the shaft clearing the apex of the posterior condyle. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the shaft of the combination of Justin in view of Chiang and in further view of Hoffman wherein the first distance is equal to or greater than the posterior condyle height such that the driver is engageable with a fastener along the distal fastener axis with the intermediate portion of the shaft clearing the apex of the posterior condyle, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

It is noted that claims 10 and 6 have been taught above (see claims 7-9).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cicierega et al. (6005018) in view of Chiang (5732606) and in further view of Hoffman (7131973).

Cicierega teaches a method of attaching an augmentation block to femoral knee prosthesis (see figs 7-9), the method comprising providing a femoral knee prosthesis having a patellar flange (34) and a fastener receiving portion (35) opposite the patellar flange for receiving a fastener along a fastener axis transverse to the patellar flange (see fig. 8), the patellar flange having a patellar flange height measured from the fastener axis to an apex of the patellar flange (note that the apex is located most clearly shown in fig. 9); providing an augmentation block (80) positionable adjacent the fastener receiving portion; providing a fastener (16) engageable with the fastener receiving portion to fasten the augmentation block in place; positioning the augmentation block adjacent the fastener receiving portion; engaging the fastener with the fastener receiving portion (see figs 7-9 and col. 6 lines 5-26). Cicierega teaches the claimed invention except for explicitly teaching the driver required by claim 1, engaging the driver with the fastener along the fastener axis and rotating the driver shaft. However, it is noted that using a driver to drive fasteners into prosthesis is well known in the art and it would have been obvious to one of ordinary skill in the art at the time of the invention that any driver mechanism can be used to drive the fasteners of Cicierega into the prosthesis of Cicierega. Chiang teaches a flexible screwdriver (see fig. 3) comprising a shaft having a fastener engaging end (50), a driven end (10), an intermediate portion (40), the shaft structured and arranged such that during application of the rotational

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forces to the driven end the intermediate portion rotates about the longitudinal axis (see fig. 3 and col. 1 lines 30-45), in order to provide a driver that is easily used to drive a fastener (see col. 1 lines 10-19 and 22-29). It would have been obvious to one of ordinary skill in the art at the time of the invention to drive the fastener of Cicierega into the prosthesis of Cicierega with the driver of Chiang in order to provide a system that allows easy implantation of prosthesis.

The combination of Cicierega in view of Chiang teaches the claimed invention except for explicitly stating the engaging end having a longitudinal engaging end axis, the shaft having an intermediate portion between the engaging end and the driven end that is offset radially from the engaging end axis. It is noted that Chiang does teach a flexible shaft that is bendable to form a curved shape in order to reach the fastener. Hoffman teaches a driver with shaft having a fastener engaging end 240, a driven end (226), an intermediate end (232), the engaging end having a longitudinal engaging end axis (see fig. 3A), the shaft having an intermediate portion between the engaging end and the driven end that is offset radially from the engaging end axis (see fig. 3A), in order to provide a shaft that is shaped to drive the fastener and allow insertion into areas difficult to access (see col. 5 lines 47-61 and note that Hoffman teaches different shapes of the shaft in figs. 3A and 13). It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the shaft of the combination of Cicierega in view of Chiang with a driver with shaft having a fastener engaging end 240, a driven end (226), an intermediate end (232), the engaging end having a longitudinal engaging end axis (see fig. 3A), the shaft having an

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intermediate portion between the engaging end and the driven end that is offset radially from the engaging end axis (see fig. 3A), in further view of Hoffman, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a driver with a shaft that allows for easy insertion. In re Dailey and Eilers, 149 USPQ 47 (1966).

As for rotating the driver to drive the fastener while clearing the apex of the patellar flange with the intermediate portion of the shaft, the height being a distance equal or greater than the patellar flange height, it is noted that it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the shaft of the combination of Cicierega in view of Chiang and in further view of Hoffman wherein the height is a distance equal or greater than the patellar height to allow for rotating the driver to drive the fastener while clearing the apex of the patellar flange with the intermediate portion of the shaft, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Response to Arguments

Applicant's arguments with respect to claims 1, 4 and 6-11 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TARA R. GEORGE whose telephone number is (571)272-3402. The examiner can normally be reached on M-F from 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TRG

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733